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13.12.79-US-102820 *(25.06.81)* A61m-05/14

Portable insulin-dispensing system uses tubular reservoir - which is easily removed and replaced, storing one week's supply

D/S: N(AU DE GB JP SE) + E(DE FR GB)

Portable system is described for delivering insulin at a predetermined rate into the body of the wearer through a needle (28). The insulin is contained in a tubular reservoir connected (42) at one end to the needle. The other end of the tubing is engaged by a powered positive displacement metering assembly (22), having a driven take-up spool (50) which rotates anti-clockwise.

As a result the end of the tubing is flattened between squeeze rollers (56) increasing the fluid pressure in the reservoir and displacing fluid through the connector (42) into the needle. The drive motor may be controlled by a microprocessor programmed to provide intermittent or continuous varying drive rates.

The reservoir tubing is thin-welled, of circular cross-section and of a sterile sanitary material such as biaxially oriented polyethylene terephthalate or polyurethane or polyethylene. The distance between the ends of the tubing is predetermined and it is dispersed in finger-like loops (48). These may be disposed in a coplanar array and a week's supply of insulin is stored.(36pp1199).

(E)ISR: GB-862872 IT-482243 US3198385 US3327898 US3471885.

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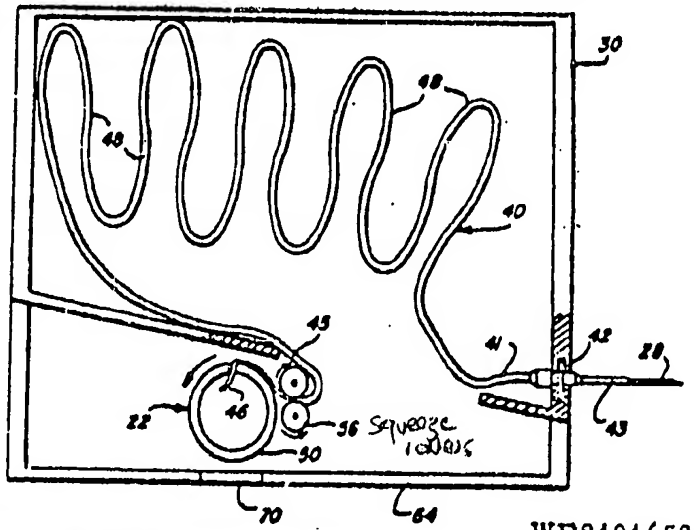

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(71) Applicants; and
(72) Inventors: LOEB, Marvin, P. [US/US]; 7350 North Washtenaw, Chicago, Il 60645 (US). CEPURITIS, Talivaldis [US/US]; 521 Brier Street, Kenilworth, IL 60043 (US).

(74) Agent: STAPLES, James, G.; Baker & McKenzie, Prudential Plaza, Chicago, IL 60601 (US).

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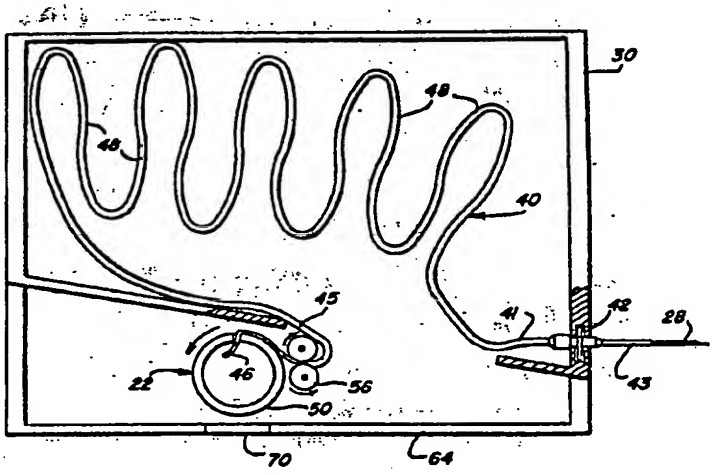
(54) Title: WEARABLE INSULIN INFUSION SYSTEM HAVING A TUBULAR RESERVOIR AND A POSITIVE DISPLACEMENT METERING MEANS

(57) Abstract

A wearable infusion system for delivering a fluid medication such as insulin to a patient through a needle, cannula or catheter (28). The infusion system includes a medication-filled elongate, thin-walled tubular reservoir (40) and a positive displacement metering assembly (22) operated by a power source under the control of a controller such as a microprocessor (24). The positive displacement metering assembly (22) draws the reservoir (40) inwardly between squeeze surfaces (56) which forces the medication toward the remote end where it discharges through an associated cannula, catheter or needle (28) into a patient. The rate and frequency at which the metering assembly is operated controls the rate and frequency at which the medication is delivered to the patient. The tubular reservoir defines a plurality of loops (48) so that a maximum amount of fluid medication may be disposed in a housing.



WEARABLE INSULIN INFUSION SYSTEM HAVING A TUBULAR RESERVOIR AND A POSITIVE DISPLACEMENT METERING MEANS

Background of the Invention

This invention relates to wearable infusion systems for delivery of fluid medications, and especially to one which is suitable for the infusion of insulin.

Considerable research has been directed to improving systems for administering insulin, a pancreatic hormone, to patients whose own body does not adequately or properly respond to shifting blood-sugar levels. Whereas a properly functioning pancreas will automatically respond to changes in blood-sugar level to produce and release the necessary insulin, the pancreas of a person such as a diabetic does not do so. Therefore, the administration of insulin from an external source to such persons is necessary.

Insulin deficiency is treated in a variety of ways, depending on the patient. Oral medication can be taken by some diabetics. Daily insulin injections can be taken by others. Here again, although injections may correct a quantitative deficiency, they do not provide insulin at the specific times when it is needed, and, accordingly, such patients' blood-sugar levels may fluctuate widely during the day. Such patients must constantly be on the alert for abnormalties in blood-sugar levels and must have sugar and extra doses of insulin available to them for use when necessary to avoid extreme reactions, such as diabetic comas and the like.

For some, these available possibilities are not adequate or satisfactory, and it has been recognized for some time now that an artificial pancreas

Summary of the Invention

In accordance with the present invention, an infusion system for controllably and positively delivering a drug such as insulin in fluid form at selected rates for discharge into a human body is provided. The insulin may be infused continuously or intermittently and subcutaneously, intraperitoneally or into an artery or vein, and may be done automatically. The present system also permits the patient to elect to have an augmented or additional infusion (bolus) as required at a rate or rates determined in advance by the prescribing physician or based upon the patient's assessment of the sugar content of his next meal.

The present system includes an elongate, continuous, thin-walled replaceable tubular reservoir and a positive displacement metering assembly. The metering assembly is operated by a power source that can be controlled by a suitable microprocessor. The reservoir, metering assembly, power source and microprocessor or like control device are adapted to be worn by a patient as on his belt, in a shoulder bag or by strapping to an extremity or his torso.

The discharge from the reservoir is positively metered for infusion into a patient, such as through an associated needle terminated cannula or implanted catheter, as desired. When the insulin supply becomes exhausted, the reservoir and metering assembly are easily removed and replaced, and in minutes the system is ready to continue the infusion of insulin.

In a preferred embodiment the tubular reservoir is housed in a replaceable cartridge comprising an enclosure and has a first end portion terminating in a connector segment adapted to be placed in fluid

insure positive displacement of the medication, e.g., insulin, and at a constant or variable predetermined rate or rates.

Brief Description of the Drawings

FIGURE 1 is a partly schematic view of a wearable insulin infusion system according to the present invention, including a tubular reservoir having a connector for communicating the reservoir with a human body, and a powered positive displacement metering assembly under the control of a suitable controller;

FIGURE 2 is an enlarged plan view of the tubular reservoir and positive displacement metering assembly of FIGURE 1;

FIGURE 3 is a fragmentary perspective view of the positive displacement metering assembly of FIGURE 2;

FIGURE 4 is a side elevational view of the positive displacement metering assembly of FIGURE 2;

FIGURE 5 is a plan schematic view of a further embodiment of a tubular reservoir and metering assembly of this invention;

FIGURE 6 is a plan view of a further embodiment of a tubular reservoir and metering assembly of this invention;

FIGURE 7 is a side elevational view of FIGURE 6;

FIGURE 8 is a fragmentary plan view of another embodiment of a metering assembly of this invention;

FIGURE 9 is a cross-sectional view of a further tubular reservoir in accordance with this invention;

FIGURE 10 is a perspective view of a further embodiment of a metering assembly of this invention; and

material such as biaxially oriented polyethylene terephthalate. It is dimensionally stable, non-stretchable and is readily flattenable and collapsible from its circular cross-sectional configuration. Polyethylene and polyurethane tubing may also be considered for use. Tubular reservoir 40 terminates at a first end in a first end portion 41 which has a connector segment 42. Connector segment 42 is suitably anchored or secured to enclosure 30 so that it will not pull out or move with respect to the enclosure, as illustrated by FIGURE 2. Connector segment 42 is adapted to be secured, as removably secured, to an infusion means, such as a four to six inch long tubular cannula segment 43 terminating in a needle 28 for subcutaneous infusion, as in a manner to be described. The reservoir 40 may terminate in a connector segment integral therewith or assembled thereto. Similarly, the cannula segment 43 may be an integral extension of the reservoir 40 and/or the connector segment or may be separate therefrom and assembled thereto to provide an integrated connector means for securance to the needle or implanted catheter, i.e., a suitable infusion means, and to the enclosure.

The second end portion 45 preferably terminates in a sealed, flattened, tape-like segment 46 adapted to be secured to metering assembly 22 in a manner to be described. The tape-like segment 46 is of a sufficient length to be secured to the positive displacement metering assembly 22.

Intermediate the ends, i.e., between the first end portion adjacent the first end and the second end portion adjacent the other end, the tubular reservoir 40 is filled with a fluid medication such as insulin that is to be discharged into a human

collapse and flatten the wall of the tubular reservoir 40 at the bight thereby tending to increase the pressure in the tubular reservoir, causing fluid to be positively displaced toward the first end portion for discharge through the connector segment 42.

To facilitate the winding and wrapping of the collapsed and flattened portions of the tubular reservoir on the take-up spool 50, cam means are provided to reciprocate the take-up spool with respect to carrier ring 60 and axially of its length, as best illustrated in FIGURES 3 and 4. Regardless of the relative vertical position of the take-up spool and carrier ring, the squeeze rollers continue to act upon the tubular reservoir to collapse and flatten it, thereby continuously and positively to meter and displace the fluid towards the first end portion as the flattened portion of the tubular reservoir is wound upon the take-up spool. Of course, the reciprocation of the take-up spool tends to wind the flattened reservoir portions in a helical or spiral pattern, thereby minimizing the variation in the effective diameter of the take-up spool as more of the flattened tubular reservoir is wound thereon. Carrier ring 60 can also be independently rotatable with respect to shaft 50 so that squeeze rollers 56 can be positioned with respect to tubular reservoir 40 for optimum coaction therewith at any given time during the dispensing cycle.

The driven gear 58 is driven by the power source 26 which preferably includes a conventional motor 61 having a power output for driving a drive gear 62. Drive gear 62 engages driven gear 58 to positively rotate take-up spool 50. The motor may be an electrical motor or it may be a mechanical motor, e.g., a spring-driven mechanism. The motor, hence

When used for insulin infusion, the positive displacement metering assembly 22 provides for rotating the take-up spool at a rate such that the squeeze rollers collapse the tubular reservoir sufficiently to positively displace the insulin solution towards the first end portion at a rate of from about 0.000533 ml. per minute to 0.0025375 ml. per minute.

Of course, the rate at which the take-up spool rotates will depend upon the internal diameter of the reservoir 40 or, in other words, upon the volume of insulin contained per unit length of the tubular reservoir, and the rate of rotation will be easily determined by the designer. The indicated rates provide a total volume delivered for a twenty-four hour period between a minimum of about 0.4872 ml. to a maximum of about 3.654 ml. These values are based upon an insulin dilution of 1:9. At this dilution the rate of insulin infusion is between about 0.04872 and 0.3654 ml. for a twenty-four hour period which corresponds to about 0.2 to 1.5 units of insulin per hour. The rate of infusion can be adjusted, or even increased beyond the indicated amounts when so prescribed by a physician.

The secondary, faster pulse generator may increase the infusion rate for a predetermined period by increasing the speed of the drive gear 62, hence the speed of rotation of the take-up spool for a preselected time period.

The entire metering assembly 22 may be disposed in a housing 64 which is removably connected to the enclosure 30. In that instance, the tape-like end segment 46 will be suitably threaded with respect to the squeeze rollers and take-up spool and wound sufficiently so that the reservoir is ready for

unit to the power supply 26 and microprocessor 24 at one end, and the connector segment and cannula segment to the infusion means at the other end, and the reverse is undertaken when the insulin supply in the reservoir has been depleted. To indicate that the supply is nearing depletion, it may be desirable to provide a signal. One such signalling means may comprise colored or other visible portions on the tubular reservoir which signify 12 hours, 6 hours and 3 hours of supply remaining, respectively, and which are viewable through a window 70 adjacent the take-up spool. Alternatively, an end portion of the tubing may be provided with a conductive material, such as a conductive metal coating in the form of a band or bands, which, as it is taken up on the take-up spool, is sensed, as by a proximity sensor associated with the microprocessor, which in turn audibly or visibly signals that the supply remaining is sufficient for say three hours. The signalling means may comprise markings like those used on common insulin syringes or magnetically encoded markings readable by a user or by a sensor.

The embodiment of FIGURE 5 is similar in most respect to that of FIGURES 1 to 4. Its principal differences are in the disposition of the loops of the tubular reservoir and in the support for the metering means.

As seen in FIGURE 5, the tubular reservoir 140 has a fan-like disposition in plan view. Reservoir 140 has a plurality of loops 148 which are finger-like in configuration and has a connector 142 and a cannula segment 143 terminating in a needle 128 at one end portion and a sealed, tape-like segment 146 at the other end. The tape-like segment is adapted to be threaded between squeeze rollers 156

least one of the loops is in a plane different from the other loops so that, as the take-up spool nears the end of the tubular reservoir 240, it will not kink. It is also preferable in this embodiment that a slide guide 257 be positioned adjacent the take-up spool and squeeze rollers, thereby to permit the loops to slide past the take-up spool 250 and squeeze rollers 256 without being acted upon by them prior to their being drawn into the bight of the squeeze rollers 256.

In the embodiment of FIGURE 8, a single squeeze roller 356 is provided. It cooperates with take-up spool 350 to provide a pair of squeeze surfaces to squeeze a tubular reservoir 340 therebetween. The squeeze roller 356 and take-up spool 350 serve both to take up the end of the tubular reservoir and to wind the tubular reservoir 340 on the take-up spool, and to collapse and flatten the tubular reservoir, as did the pairs of squeeze rollers shown in the embodiments of FIGURES 1-7.

The tubular reservoir illustrated in the embodiments of FIGURES 1-8 were described as being generally circular in cross section. However, tubular reservoirs having other cross-sections may be used and in FIGURE 9, a generally elliptical tubular reservoir 440 is illustrated. It too is of a dimensionally stable, sterile and sanitary material.

Although the positive displacement metering assemblies described so far incorporate a driven take-up shaft or spool, it is also possible to drive squeeze rollers instead of, or in addition to, the take-up spool. As seen in FIGURE 10, a fragmentary metering assembly is seen to comprise a pair of spaced apart squeeze rollers 456 and a take-up spool 450. Each roller has a knurled surface to grippingly

between the reservoir and needle and also provides the means for anchoring to the housing so that pull-out does not occur. The assembly may otherwise be the same as that of FIGURES 1 to 4.

The foregoing description and the drawings are intended as illustrative and are not to be taken as limiting. Still other variations and rearrangements of parts within the spirit and scope of this invention are possible and will be readily apparent to those skilled in the art who are familiar with the foregoing description and drawings.

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thin-walled tubular reservoir defines a plurality of loops between said first and second end portions.

5. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein a plurality of said loops are generally coplanar.

6. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein said loops are of a generally zig-zag configuration.

7. A system for controllably delivering fluid at selected rates of discharge into a human body in accordance with claim 5 wherein said loops are generally finger-like in configuration.

8. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein said loops are generally circular in configuration.

9. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 8 wherein said generally circular loops comprise a continuous coil.

10. a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 8 wherein a plurality of said loops lie generally in a single plane.

11. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 wherein said powered positive displacement metering assembly includes a pair of closely spaced squeeze surfaces for flattening said tubular reservoir to displace fluid toward said first end portion.

12. A system for controllably delivering fluid at selected rates for discharge into a human

surfaces are mounted on a carrier, and further comprising means mounting said take-up spool for movement axially of said carrier.

19. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 11 wherein said thin-walled tubular reservoir defines a plurality of loops between said first and second end portions.

20. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 further comprising means for selectively controlling the positive displacement metering assembly thereby controllably to vary the rate at which said preselected length is reduced and flattened, thereby selectively to vary the rate at which fluid is displaced toward said first end portion.

21. A replaceable cartridge for use in a system for controllably delivering fluid at selected rates for discharge into a human body, said cartridge comprising

an enclosure,

an elongate, continuous, readily flattenable thin-walled tubular reservoir in said enclosure and having a first end portion and a connector means adjacent a first end and a second end portion adjacent the other end, said reservoir being filled with a fluid between said end portions and having a preselected length between said end portions, and

said connector means being secured to said enclosure at said first end portion, said connector means being adapted to be placed in fluid communication with means for discharging said fluid into a human body, and

27. A replaceable cartridge for a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 26 wherein said metering assembly further comprises a take-up spool for winding said tubular reservoir thereon as said preselected length is reduced and flattened.

28. A replaceable cartridge for a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 27 wherein said squeeze rollers are mounted on a carrier, and means mounting said take-up spool for movement axially of said carrier to promote helical winding of said flattened tubular reservoir on said take-up spool.

29. A system for controllably delivering fluid at selected rates for discharge into a human body, comprising

a replaceable enclosure,

an elongate, continuous, readily flattenable thin-walled tubular reservoir in said enclosure and having a first end portion adjacent a first end and a second end portion adjacent the other end, said reservoir being filled with a fluid between said end portions and having a preselected length between said end portions, said reservoir having a connector means secured to said enclosure at said first end portion, said connector means being adapted to be placed in fluid communication with means for dis- charging said fluid into a human body,

said second end portion defining a segment adapted to be secured to a metering assembly,

a positive displacement metering assembly adjacent said second end portion for securing and moving said second end portion in a direction to

squeeze surfaces comprise a pair of closely spaced squeeze rollers adjacent said take-up spool.

35. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 34 wherein said squeeze rollers are mounted on a carrier, and further comprising means mounting said take-up spool for movement axially of said carrier.

36. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 29 further comprising a controller for selectively controlling the power source thereby controllably to vary the rate of movement of said tubular reservoir and the rate at which said preselected length is reduced and flattened, thereby selectively to vary the rate at which fluid is displaced toward said first end portion.

37. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 29 wherein said positive displacement metering assembly is mounted on said replaceable enclosure.

38. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 29 wherein said metering assembly is in said enclosure and said second end portion segment is secured to said metering assembly.

4. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 wherein said thin-walled tubular reservoir defines a plurality of loops between said first and second end portions.

5. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein a plurality of said loops are generally coplanar.

6. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein said loops are of a generally zig-zag configuration.

7. A system for controllably delivering fluid at selected rates of discharge into a human body in accordance with claim 5 wherein said loops are generally finger-like in configuration.

8. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 4 wherein said loops are generally circular in configuration.

9. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 8 wherein said generally circular loops comprise a continuous coil.

10. a system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 8 wherein a plurality of said loops lie generally in a single plane.

11. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 1 wherein said means for flattening said tubular reservoir includes a pair of closely spaced squeeze surfaces for flattening said tubular reservoir to displace fluid toward said first end portion.

vary the rate at which said preselected length is reduced and flattened, thereby selectively to vary the rate at which fluid is displaced toward said first end portion.

19. A system for controllably delivering fluid at selected rates for discharge into a human body, comprising

a replaceable enclosure,

an elongate, continuous, readily flattenable thin-walled tubular reservoir in said enclosure and having a first end portion adjacent a first end and a second end portion adjacent the other end, said reservoir being filled with a fluid between said end portions and having a preselected length between said end portions, said reservoir having a connector means secured to said enclosure at said first end portion, said connector means being adapted to be placed in fluid communication with means for dis- charging said fluid into a human body,

said second end portion defining a segment adapted to be secured to a metering assembly,

a positive displacement metering assembly adjacent said second end portion, said metering assembly including a take-up spool for securing and moving said second end portion in a direction to reduce said preselected length and means for flattening said tubular reservoir as it moves in said direction, thereby positively to displace fluid toward said first end portion to force fluid through said connector means toward said means for discharging said fluid into a human body, and

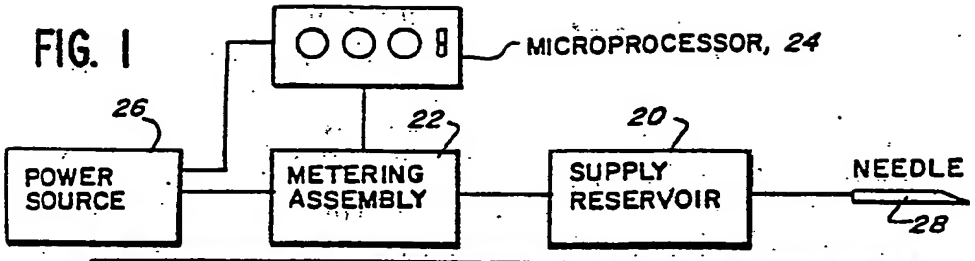
a power source for operating said metering assembly.

20. A system for controllably delivering fluid at selected rates for discharge into a human

26. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 19 wherein said positive displacement metering assembly is mounted on said replaceable enclosure.

27. A system for controllably delivering fluid at selected rates for discharge into a human body in accordance with claim 19 wherein said metering assembly is in said enclosure and said second end portion segment is secured to said metering assembly.

FIG. 1



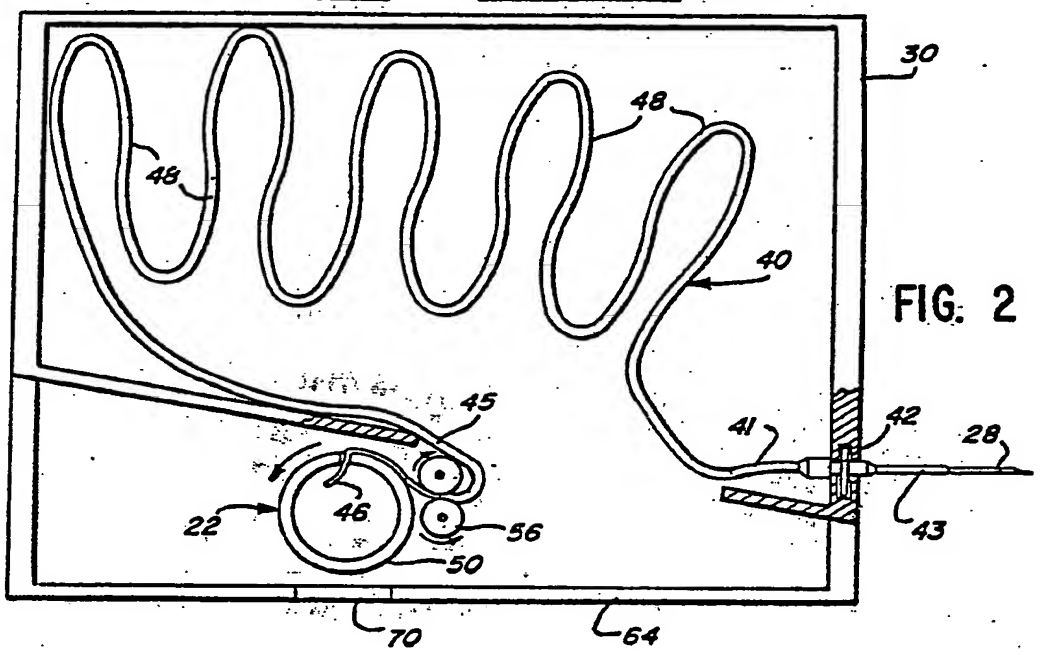


FIG. 2

FIG. 3

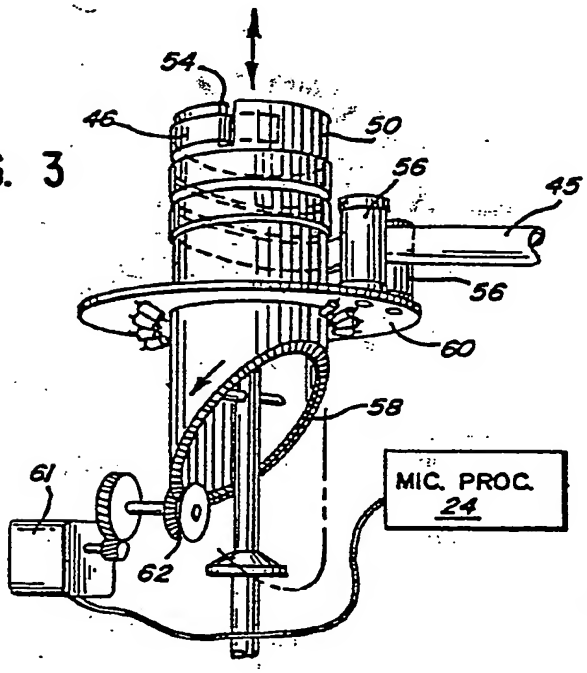
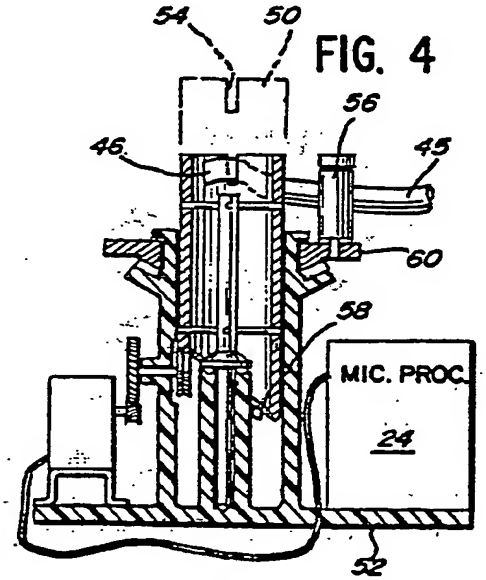


FIG. 4



INTERNATIONAL SEARCH REPORT

International Application No PCT/US80/01630

I. CLASSIFICATION OF SUBJECT MATTER (If several classification symbols apply, indicate all) [3]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int. Cl. A61M 5/14
U.S. Cl. 128/214

II. FIELDS SEARCHED

Minimum Documentation Searched [4]

Classification System	Classification Symbols
U.S.	128/214R, 214E, 214F; 242/86, 67.2; 222/102, 209

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched [5]

III. DOCUMENTS CONSIDERED TO BE RELEVANT [14]

Category *	Citation of Document, [16] with indication, where appropriate, of the relevant passages [17]	Relevant to Claim No. [18]
X	GB, 862,872, Published 15 March 1961	1-38
X	IT, 482,243, Published 25 June 1953	1,16-18 26-28,32-35
X	US,A, 3,198,385, Published 03 August 1965	1-3,11-13, 20,32,36
X	US,A, 3327898 Published 27 June 1967	4-10,21-23, 25,31
X	US,A, 3,471,885, Published 14 October 1969	14-16,18,29 33-35

* Special categories of cited documents: [15]

"A" document defining the general state of the art

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"L" document cited for special reason other than those referred to in the other categories

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but on or after the priority date claimed

"T" later document published on or after the international filing date or priority date and not in conflict with the application, but cited to understand the principle or theory underlying the invention

"X" document of particular relevance

IV. CERTIFICATION

Date of the Actual Completion of the International Search [2]	Date of Mailing of this International Search Report [2]
16 March 1981	24 MAR 1981
International Searching Authority [1]	**Signature of Authorized Officer [20]**
ISA/US	R. McKelvey

Form PCT/ISA/210 (second sheet) (October 1977)